DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 07 2009

I-010697-X-0098-CE

U.S. Fish & Wildlife Service
Aquatic Animal Drug Approval Partnership Program
Attention: David Erdahl, Ph.D.
Branch Chief
4050 Bridger Canyon Road
Bozeman, MT 59715

Re: Claim for a categorical exclusion for investigational use of Aquaflor

Dear Dr.Erdahl:

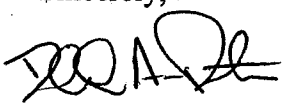
Your claim for a categorical exclusion from the requirement to prepare an environmental assessment (EA) dated April 30, 2009, meets the criteria for categorical exclusion (CE). The CE claim is for the investigational use of Aquaflor (florfenicol) medicated feed. The drug is proposed for investigational use in freshwater and marine fish for several new indications. We note that your submission included a request for an amended authorization that was submitted with your claim for categorical exclusion (X submission). Please note that this letter only acknowledges your claim for a categorical exclusion. Your other request for an amended authorization will be addressed in a separate letter (D-0096). In the future, please submit only one request per letter.

Your claim of categorical exclusion for the investigational use of florfenicol falls within the CE in 21 CFR 25.33 (e). Your submission stated that to your knowledge no extraordinary circumstances exist that may significantly affect the human environment. Therefore, neither an EA nor an environmental impact statement (EIS) is required. You are responsible for complying with the Federal Clean Water Act as implemented under the National Pollutant Discharge Elimination System (NPDES), as well as any applicable ground-water pollution requirements, for all investigational sites covered under this INAD. For the investigational site(s), site investigators should contact the appropriate Environmental Protection Agency (EPA) or State NPDES permitting authority to determine if the investigational use and discharge of florfenicol under the INAD should be reported [see 40 CFR Parts 451.1, 451.2, and 451.3(a)]. In addition, this CE from the preparation of an EA and an EIS does not relieve you of the responsibility for determining and meeting all other Federal, State, and local environmental and occupational laws and regulations that apply to the manufacturing, use, and disposal of investigational drugs.

This CE only covers the investigational use of this product. An EA or a separate request for a CE will also be necessary for the approval of a new animal drug application (NADA) for this product. As appropriate, please contact the Environmental Safety Team as soon as possible to discuss the information needed for the NADA.

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact me at (240) 276-8177. You may also contact Charles Erikson, Leader, Environmental Safety Team at (240) 276-8173.

Sincerely,



Donald A. Prater, DVM
Director, Division of Scientific Support
Office of New Animal Drug Evaluation
Center for Veterinary Medicine